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(54) Method and apparatus for assessing the structure and mechanical integrity of osseous systems

(57) A method and apparatus for assessing the mechanical and structural integrity of osseous systems for example the progress to completion of fracture union of a fractured bone. The method involves stimulating the bone to set up vibrations in the bone and then monitoring the resulting vibrations from the bone in such a way that an accurate assessment of the integrity of the bone can be made. This may be done by either stimulating the bone by mechanical impulse and detecting the changes in transmission of vibration from one point to another in the bone, or stimulating the bone with a sinusoidal wave form and monitoring the changes in resonant frequencies of the bone parts under investigation.

The disclosed invention has the attributes that it yields a measure of the mechanical state of bone and that measure is quantitative. Moreover it yields data of similar quality whether the bone is intact, disrupted, healing or the site of an implant, splint or prosthesis of whatever material, and has applications as a research tool or clinical monitor of skeletal changes.

Fig. 1.

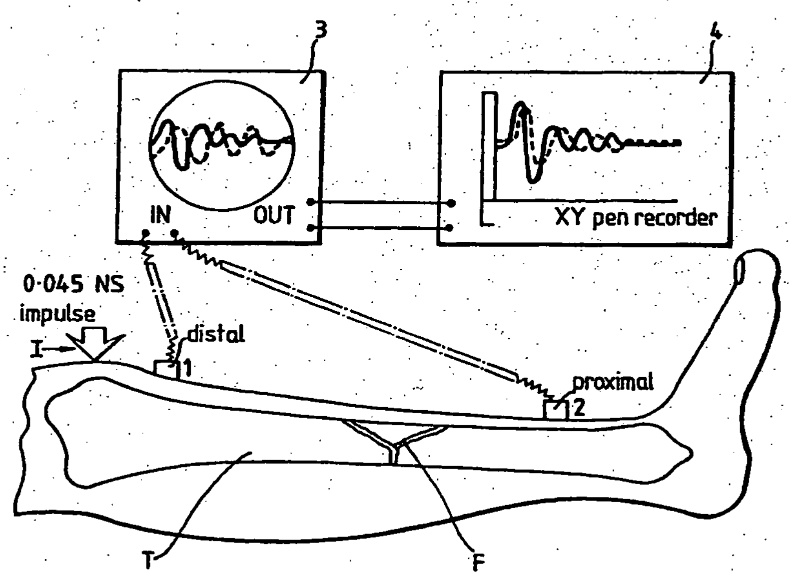

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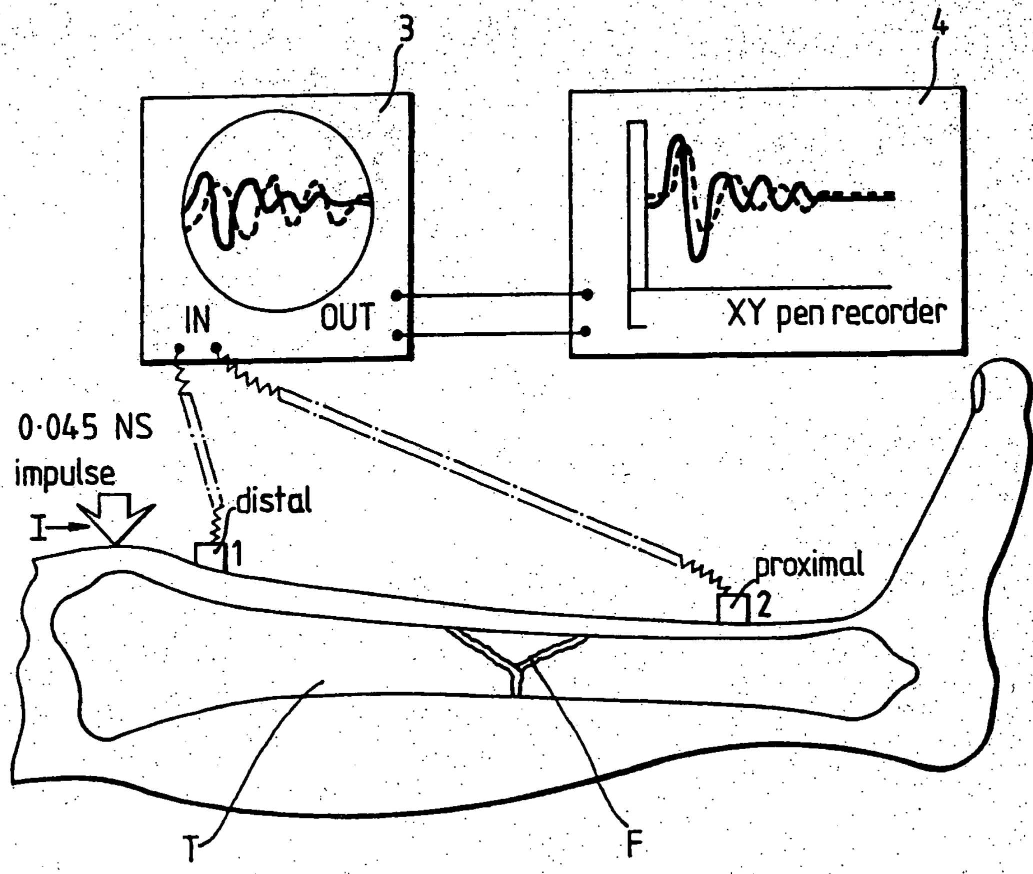
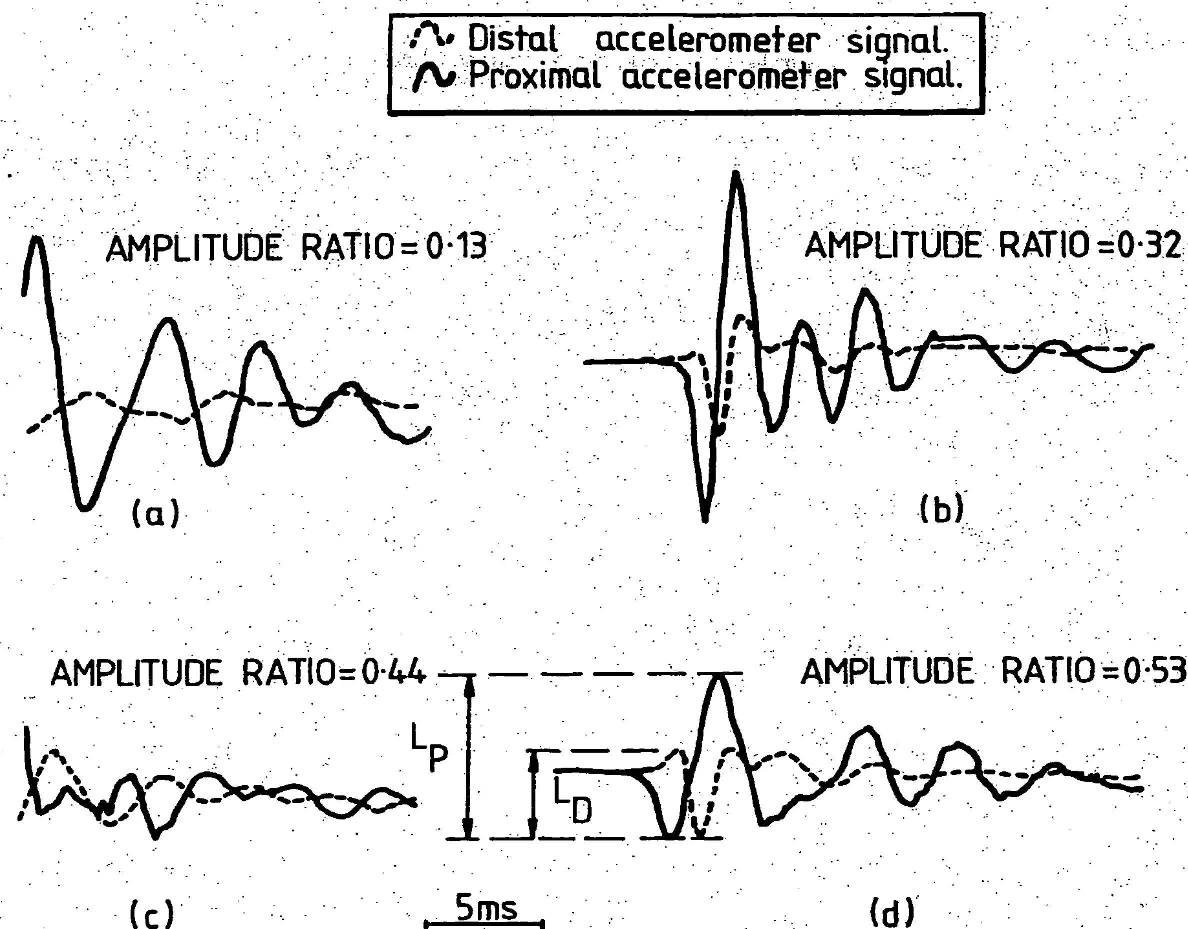
Fig. 1.



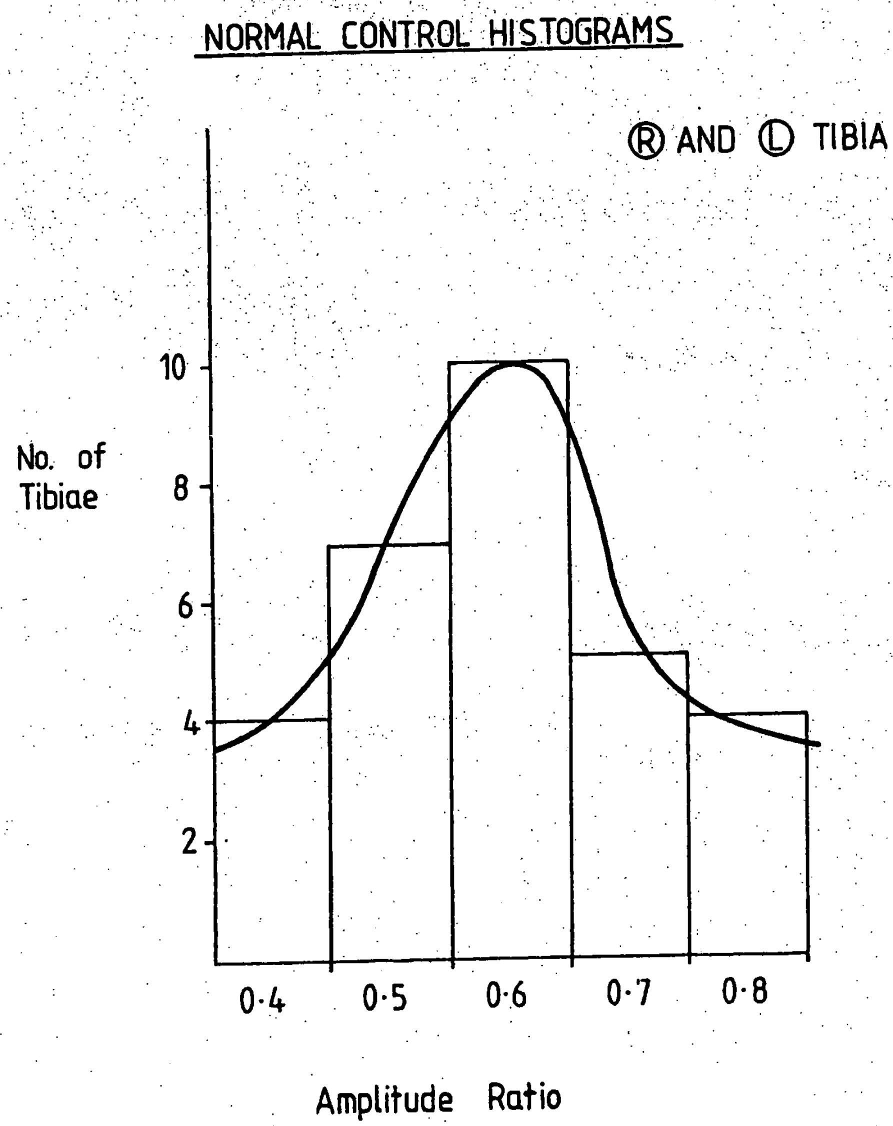
3
4
IN
OUT
XY pen recorder
0·045 NS
impulse
I
distal
1
proximal
2
T
F



Distal accelerometer signal.
Proximal accelerometer signal.
AMPLITUDE RATIO=0·13
(a)
AMPLITUDE RATIO=0·32
(b)
AMPLITUDE RATIO=0·44
(c)
L_P
L_D
5ms
AMPLITUDE RATIO=0·53
(d)

Fig. 2.

Fig. 3.


NORMAL CONTROL HISTOGRAMS
® AND Ⓛ TIBIA
No. of Tibiae
10
8
6
4
2
0·4
0·5
0·6
0·7
0·8
Amplitude Ratio

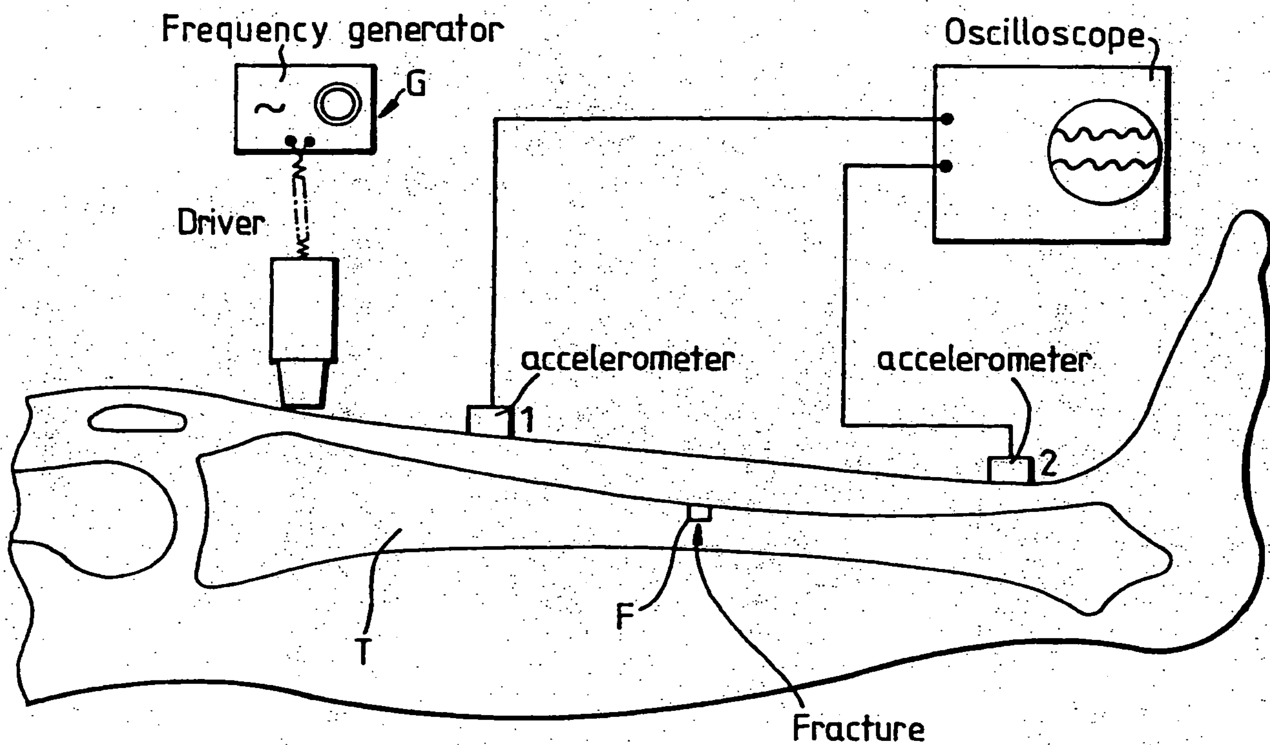

Frequency generator
G
Driver
Oscilloscope
accelerometer
1
accelerometer
2
T
F
Fracture

Fig. 5.

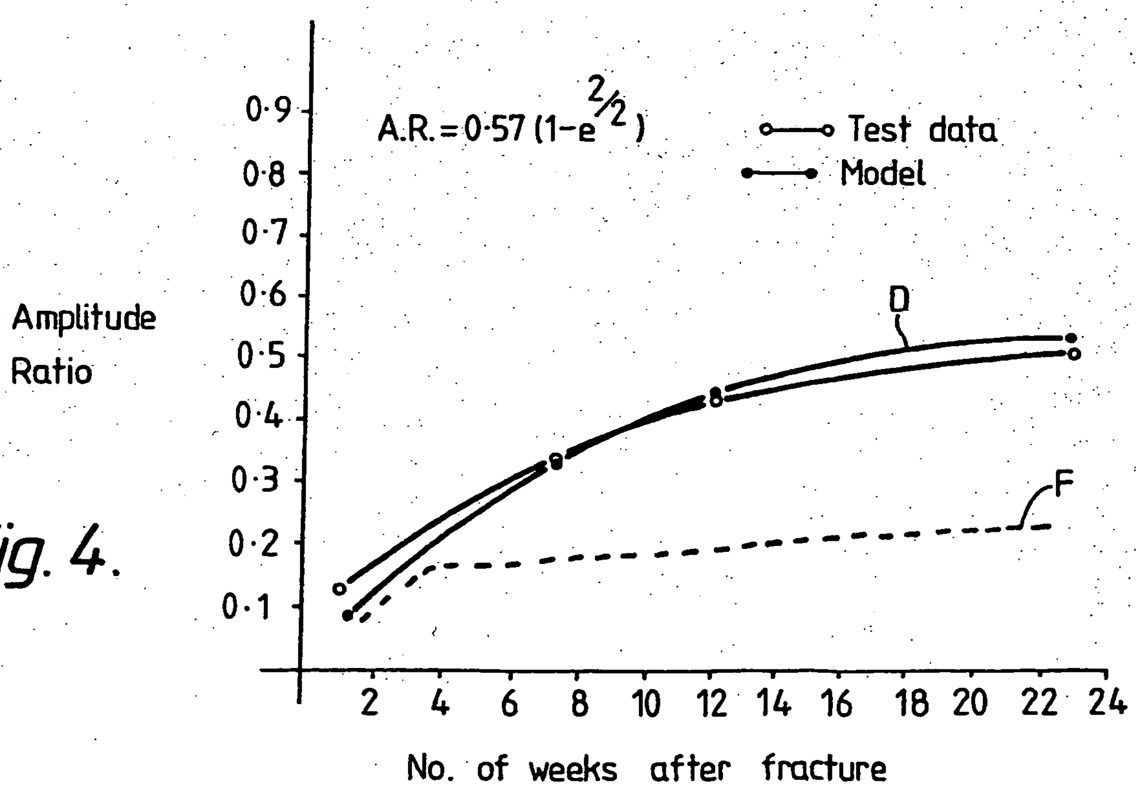

A.R.=0·57 (1−e^2/2)
Test data
Model
Amplitude Ratio
0·9
0·8
0·7
0·6
0·5
0·4
0·3
0·2
0·1
D
F
2
4
6
8
10
12
14
16
18
20
22
24
No. of weeks after fracture

Fig. 4.

5/6

BLOCK DIAGRAM OF SYSTEM.

Fig. 6.

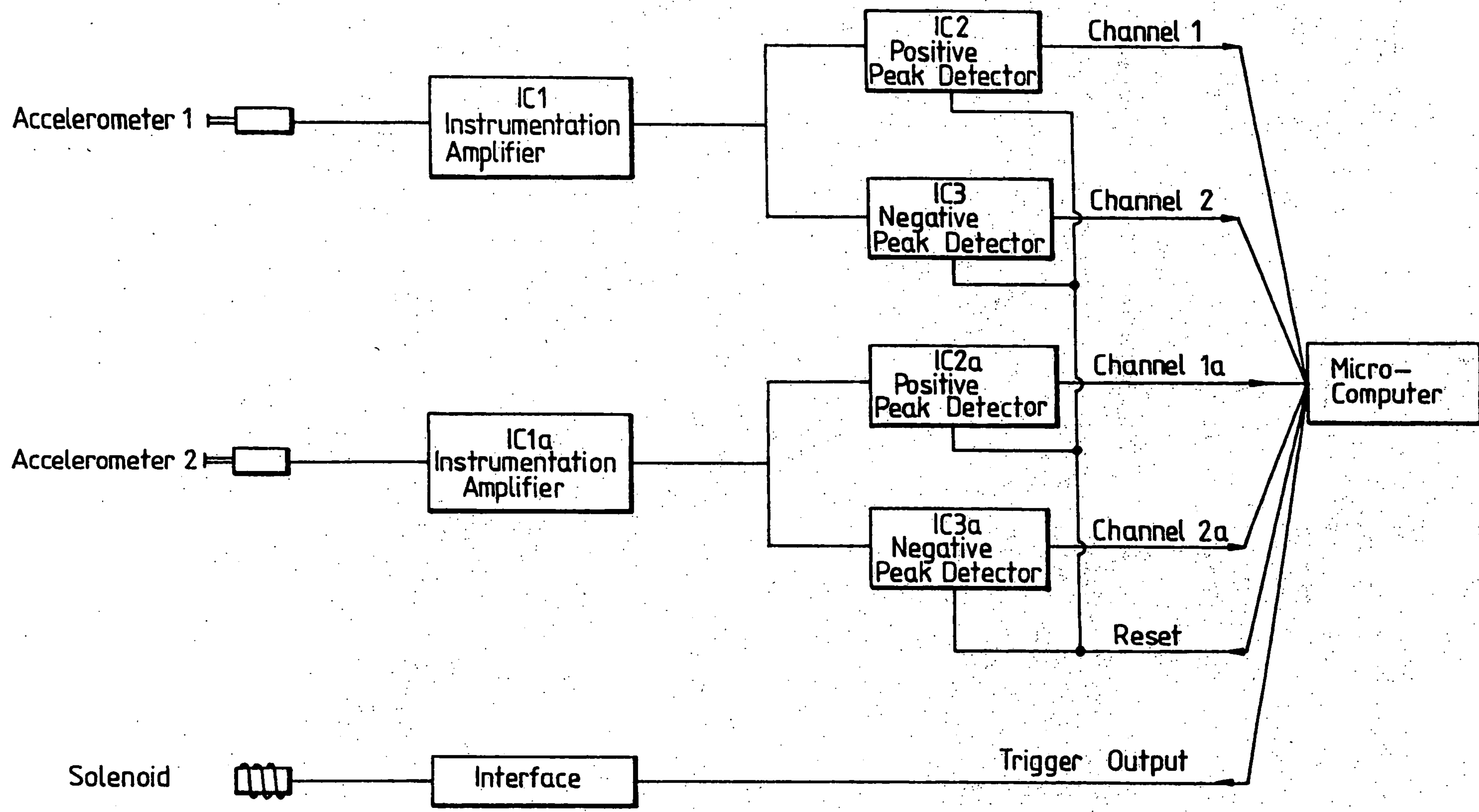
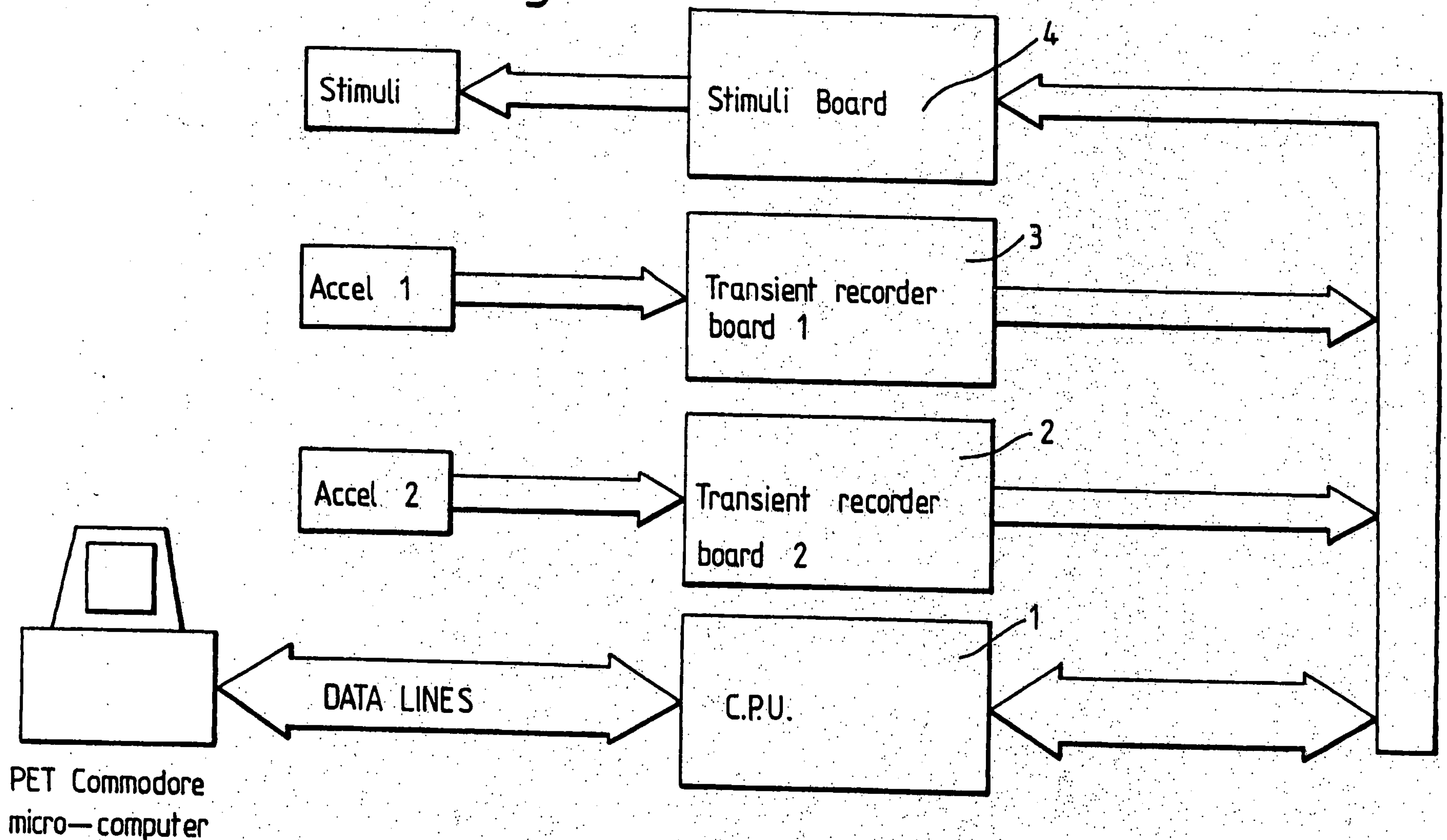


Fig. 7.



Schematic diagram of fracture monitor

SPECIFICATION

Method and apparatus for assessing the structure and mechanical integrity of osseous systems

Field of the invention

The present invention relates to a method and apparatus for assessing the structural and mechanical integrity of osseous systems, which includes the assessment of both the rate and extent of the progress of fracture union and the investigation of the stability of composite systems where bone is interfaced with implants such as are used to fix fractures or in the treatment of patients by joint replacement.

Background art

In the assessment of bone fracture union for example, simple clinical determination is useful once the point of union has been reached, but has little value in predicting behaviour in its progress to union. However with the advent of clinical radiology it is now possible for the fracture surgeon to see an image of the developing callus as the fracture heals. Nevertheless since that image relies for its production on the mineralisation of callus, the disadvantage arises that the radiographic appearance lags behind the actual evolution of the callus mass. A more important failing of radiographs however is that they are an unreliable predictor of failure of union. For example some fractures fail to unite even in the presence of abundant callus.

Another drawback of radiographic assessment is the undesirable dose of radiation given to the patient.

It is therefore desirable to provide a method of assessing fracture union which records at a specific time the actual state of the callus in terms of its mechanical properties. Also such a method should permit the early and accurate prediction of failure of progress to union, so that the necessary treatment to augment failure can be instituted immediately without the delay which is incurred by present methods.

Over recent years the mechanical properties of bone have been investigated by various means, but vibration and wave propogation techniques are the only methods that have shown much promise for clinical use, for example in the evolution of fracture healing and the assessment of bone quality.

The analysis of the vibratory behaviour of bone requires the measurement of its acceleration in response to a known applied mechanical force in the form of, for example, an impulse or a continuous vibration. Such an applied mechanical force may be delivered by any of several simple methods and the resulting acceleration measured by an accelerometer mounted on the bone. In the live human subject it is not generally possible and/or recommended to place an accelerometer directly on the bone to measure its response and the use of a skin-mounted device is therefore essential.

Investigations have shown however that the effects of soft tissue i.e. skin thickness, considerably attenuates or damps the response from the accelerometer where skin-mounted measurements have been attempted, thus rendering the method unreliable.

This has been demonstrated by comparing recorded signals from accelerometers mounted on the skin, with those taken from accelerometers mounted on the bone. The signals from the former have been shown to bear little relationship to the latter, as would be required for the method to be clinically useful.

It is therefore an object of the present invention to provide means for assessing the structure and mechanical integrity of osseous systems particularly bone fracture union which does not suffer from the above-stated shortcomings of present clinical techniques, by employing a more direct and precise quantitative analysis of the vibrational effects resulting from a delivered applied force to the bone, and wherein *inter alia* these vibrational effects are not reduced in strength or intensity by the damping effects of skin thickness to such a degree as to render the signal unrecognizable for measurement purposes.

According to one aspect of the invention there is provided an apparatus for assessing the mechanical and structural integrity of bone such as bone fracture union comprising means for vibrating the bone, and means for monitoring the vibratory response from the bone to determine the presence of required mechanical and structural integrity.

Advantageously and in the case of application of the apparatus to assessing bone fracture union, the vibratory response from the bone is monitored by a vibratory responding means, such as an accelerometer, which may be positioned to either side of the fracture, the vibratory responding means being weighted or preloaded by a predetermined amount to compensate for the effects of skin thickness on the received vibratory response.

Preferably the vibratory stimulus is a mechanical impulse and the ratio of the largest amplitude in the signals recorded by the accelerometers is obtained by suitable means at predetermined intervals to provide a measure of the state of fracture union.

Alternatively the vibratory stimulus may be in the form of a continuous vibratory sinusoidal mechanical force, and the difference between the first mode natural frequency of each fractured element is obtained by suitable means to provide a measurable quantity against which to assess the progress of fracture union.

With this method the step of obtaining the ratio between the respective vibratory signals from the two vibratory responding means, or the difference in natural mode frequency, cancels out extraneous and unwanted factors (such as limb dimensions) which would otherwise complicate the measurement assessment of the progress of bone fracture union, and secondly, the weighting or preloading of the responding means diminishes the excessive damping effects on the vibratory signals caused by transmission of the signals through the skin tissue surrounding the fractured bone.

It has been found preferable to weight or preload the vibratory responding means, advantageously in the form of accelerometer, by an amount which is related to the thickness of the soft tissue between the bone and the measuring device, and having a lowest threshhold value of preload sufficient to overcome the damping effects of the tissue.

To avoid having to employ weighted or preloaded accelerometer probes in both the above forms of bone stimulus to monitor vibratory response, Doppler ultrasonic sound detectors may be used, and the maximum Doppler shift frequencies above and below the fracture obtained to provide an assessment of union.

According to another aspect of the invention there is provided a method of assessing bone fracture union, comprising applying vibratory stimulus to a fractured bone, and monitoring vibratory response from the bone thereby to determine progress to complete fracture union.

Brief description of the drawings

The invention will now be described by way of example with reference to a preferred embodiment of the invention illustrated in the accompanying drawings wherein

Figure 1 is a schematic illustration of suitable apparatus for assessing progress of bone fracture union according to the invention;

Figure 2 shows representative vibratory signal recordings taken from a group of patients with tibial shaft fractures at various stages of healing using the apparatus of Figure 1;

Figure 3 is a histogram of the amplitude ratios of vibratory signals obtained with the apparatus of Figure 1, from thirty normal tibiae;

Figure 4 is a graph of time-after-fracture plotted against amplitude ratio comparing those tibiae that went on to satisfactory union with tibiae that did not progress to satisfactory union; and

Figure 5 is a schematic illustration of an alternative suitable apparatus for assessing progress of bone fracture union according to the frequency mode aspect of the invention.

Best modes of carrying out the invention

Apparatus for assessing the progress of fracture union of a skeletal element, in this case the human tibia, is shown in Figure 1.

It comprises a pair of accelerometers 1 and 2 shown mounted on the anteromedial subcutaneous surface of a tibia T respectively to either side of a tibial fracture F. In the operational example shown the accelerometer 1 is positioned 60 mm distal to the tibial tubercle, whilst the accelerometer 2 is 60 mm proximal the medial malleolus.

To set up the required vibration in the tibia an impluse I of 0.045 Ns may be applied to the tibial tubercle, by means not shown, and the resulting vibrational effects in the tibia are displayed on an oscilloscope 3 coupled to the accelerometers, the oscilloscope 3 being set simultaneously to display two traces respectively representative of the signals from the accelerometers 1 and 2. An x-y pen recorder 4 is connected to the oscilloscope 3 to provide a permanent record of the vibratory signal.

To counteract the effects of skin thickness, each accelerometer 1 and 2 is preloaded with a vertical force to such a degree that the obtained vibratory signal is comparable with a reference vibratory signal which would be obtained with the accelerometers positioned directly on the fractured bone. It has been shown that this is met when the preload is within the range 3.2 to 6 Newtons, and the required value within this range in any given case is directly proportional to skin thickness.

To test the clinical accuracy of the apparatus of Figure 1, a group of 20 patients, with unilateral diaphyseal fractures in the tibia, and normal contralateral limbs were monitored with the apparatus to assess successful fracture union.

Four typical waveform traces obtained from four patients over a period of time, from a few hours from initial injury up to six months later, are shown in Figure 2(a) to 2(d), Figure 2(a) being that from the left tibia of a 27 year old male after two weeks, Figure 2(b) from the left tibia of a 17 year old male at two weeks and corresponding to a showing of moderate callus on the radiograph, Figure 2(c) the right tibia of an 80 year old male at twelve weeks and corresponding to tenuous radiographical union, and Figure 2(d) the right tibia of a 22 year old male at eighteen weeks, clinically and radiographically solid. All the fractures were managed nonoperatively and went on to satisfactory union.

Each Figure 2(a) to 2(d) shows a dual trace of a damped waveform, that in dotted outline being the response from the distal accelerometer 2. The other damped waveform trace, in full outline, is the response from the proximal accelerometer 2 which is nonvariable and normal in all cases, that is normal with respect to that trace which would be obtained with the proximal accelerometer from a non-fractured tibia.

It will be noted that the amplitude of the waveform signal from the distal accelerometer 1 increases and becomes more distinct with time, and these changes are taken to be indicative of the restoration of the normal mechanical properties of the bone, in effect the healing process of the fracture, because the transmitting path to the relevant accelerometer for the vibrational forces within the tibia increases as the fracture closes, resulting in increased amplitude or intensities of the vibratory response.

The useful clinical measurement which can be obtained from such traces has been found to be the amplitude ratio between the respective waveforms in each trace, this being defined as the ratio of the largest amplitude of deflection L_D in the distal accelerometer trace, to the largest amplitude of deflection of the proximal accelerometer trace L_P as shown in Figure 2(d), which will always be less than unity because a proportion of the input energy is lost along the length of the intact portion of the tibia.

It will be seen from Figure 2 that the amplitude ratio increases from a low value of 0.13, Figure 2(a), representative of a fresh fracture when minimal transmission of vibration occurs across the fracture F, and the amplitude measured by the distal accelerometer 2 is near zero, to a maximum value of 0.53, Figure 2(d), at complete healing. This final ratio value is important since it has been shown to correlate closely with that ratio statistically obtained from a group of patients with normal intact tibia, and therefore when obtained in practice, can be taken to represent a true measure of the state of complete tibial fracture union, of any representative tibial fracture.

As healing progresses from the stage represented by Figure 2(a), vibration is increasingly transmitted across the fracture path, so that the amplitude of the distal accelerometer reading increases as does the amplitude ratio.

Figure 2(b) and 2(c) represent traces taken from fractures at 8 weeks and 12 weeks respectively, and having amplitude ratios 0.32 and 0.44.

This rising amplitude ratio to complete fracture union, as illustrated in Figure 2(d), has also been shown to correlate with the clinical and radiological evidence of successful union.

As mentioned earlier the typical amplitude ratio obtaining at full tibial healing in the tested group of patients with fractured tibia, compares favourably with that obtained from a statistical analysis of the vibratory responses from patients with normal intact tibia, using the apparatus of Figure 1.

The group studied in such an analysis was composed of 30 normal tibia and 15 healthy adults. The measurements taken were used to characterise the response of normal tibia and to compare the left and right bones in each individual subject.

The measured amplitude ratios from the normal group, are given in the histogram illustrated in Figure 3. It is clear that the range of result follows a normal distribution. There was no difference shown between the left and right legs of individuals, and the mean amplitude ratio was found to be 0.57 with a standard deviation of 0.11.

Controlled monitoring tests of the type discussed with reference to Figure 2 may be performed, from initial fracture to complete fracture union, on patients with normal tibiae fracture using the apparatus of Figure 1 and the results used to construct a graph of amplitude ratio against time which can then be employed by the surgeon in the field to assess fracture union of any representative tibiae fracture, as proposed herein.

A typical graph is shown in Figure 4 constructed from the results of tibiae that healed normally and those which did not progress to satisfactory union. Curve D, produced from actual test data, forms a working model against which the continuous healing of tibial diaphyseal fractures can be measured, as the results from a subject fracture, using the device of Figure 1, are obtained on the required medical time basis. Curve F depicts a typical example of what would be obtained in the instance of a non-united tibial fracture.

The curve D is exponential and reaches a plateau in 24 weeks at which time sufficient consolidation of the fracture may be judged to have taken place so rendering the mechanical properties of the bone normal. Initially the curve rises rapidly so that by 8 weeks after injury, in any fracture which is healing normally, nearly two thirds of the expected rise in amplitude ratio will have occurred.

Measurements on healing fractures using the technique described above have been made either at routine plaster changes or through windows cut from casts. Patients with removable braces have proved to be no problem.

As a method of following the progress of fracture union the technique has significant advantages over radiology. In the first place it avoids all the hazards of ionizing radiation whilst it has no known hazards that are specific to it. The information which is yielded relates to the mechanical state of the fracture at the time of the measurement. Any inference from radiographs about the mechanical state of the fracture is necessarily subjective, and in reality relates only to mineralised callus that radiographs identify and not the whole callus mass. In the first three to six weeks, radiology may yield no useful information whatever about the state of union, even though by this time the amplitude ratio may have risen a third of the way or even half way to normal. Conversely if the six week radiograph shows abundant callus, union might be expected, but if the amplitude ratio is low for example 0.1, a hypertrophic non-union is the likely outcome.

The above-described mode of carrying out the invention is concerned with subjecting the bone to a single impluse which is transmitted along the skeletal element under investigation.

In another mode of carrying out the invention the skeletal element is stimulated by a sinusoidal waveform and the first mode natural frequency of the skeletal part under study is measured directly and used to form a quantitative measure against which to assess the state of bone fracture union.

Thus in comparison to the first above-described mode of carrying out the invention, where the amount of energy transmitted along a bone is related to its structural and mechanical integrity, the second mode is based on the premise that the natural frequency of a discrete skeletal element is corrupted if that element's structural integrity is compromised, and the part then exhibits one or more different natural frequencies.

To drive the bone at its natural frequency, an electro- mechanical vibrator is applied to the skin and is driven by a sine wave generator whose output is variable in frequency, and determinable, so that the skeletal element can be driven at its natural frequency whatever that may be.

Figure 6 is a schematic illustration of an alternative suitable apparatus for assessing progress of bone fracture union, according to the frequency mode aspect of the invention. It comprises a frequency generator G for vibrating the human tibia T, by application of a continuous vibration to the tibial tubercle. A first bone vibratory responding means, in the form of an accelerometer, is applied 60 mm from the tibial tubercle and a second bone vibratory responding means is applied to the subcutaneous surface 60 mm from the medial malleolus, that is to either side of a fracture F in the tibia T.

Each bone vibratory responding means is coupled to an oscilloscope from which both signals from the accelerometers can be displayed. For the tibia, the first mode natural frequency for both proximal and distal fragments thereof is determined by stimulating the tibial tubercle at various frequencies, and observing that frequency at which the displayed sinusoidal trace of each accelerometer signal reaches its maximum amplitude.

When the tibia is fractured the two traces on the oscilloscope show that the measured natural frequency is different in the proximal and distal fragments, and that the proximal fracture has the higher frequency. The healing tibia may be visualised as two major fragments vibrating independently at first but with an interface zone which gradually becomes stiffer. As healing progresses the length of the vibrating system is effectively increased and this has the effect of depressing the natural frequency of the vibrating fragments.

The mean fall in frequency difference as the tibia heals, correlates well with clinical and radiological evidence of union, but is evident long before either of these current clinical techniques are helpful in the assessment of fracture healing.

Calculation of this mean difference over a period of time forms an accurate means for assessing bone fracture union and when the difference is extremely small or non- existent fracture healing can be said to have taken place, the natural frequency of the tibia at that time corresponding to the first mode natural frequency of an intact tibia.

A block diagram of a system for processing the data received from the accelerometers using the impulse mode of the invention is given in Figure 6. The heart of the system is a microcomputer board offering four analogue- to-digital converter inputs, and a number of digital outputs which may be used for circuit-control purposes. The inputs and outputs are all activated by computer software, which has been written specifically to perform the procedure described above.

The operating sequence is as follows: a digital trigger pulse from the computer is sent via an interface circuit to a solenoid-actuated piston. The piston is released, and impinges onto the tibia giving an impulsive stimulus of defined value. The resulting vibrations within the tibia are detected by accelerometers 1 and 2 (Bruel & Kjaer, type 4369), appropriately positioned on either side of the fracture site. The accelerometers convert these vibrations into low-level electrical signals, which are then amplified by instrumentation Amplifiers ICl and IClа. Provision is made in these circuits for the cancellation of offset potentials, and for the adjustment of amplifier gain in order to compensate for any imbalance in the sensitivities of the transducers.

The amplified accelerometer signals are then fed to the peak detector circuits, IC2 and IC3 for Accelerometer 1, IC2a and IC3a for Accelerometers 2. IC2 (IC2a) captures and stores the maximum positive value of the vibration transient, and holds it ready for use by the channel 1 (1a) analogue-to-digital converter. Similarly, IC3 (3a) captures the maximum negative amplitude of the same transient for use by the Channel 2 (2a) analogue-to-digital converter. The computer now allows conversion to take place; the timing of this process is software-controlled, so that conversion occurs within a few milliseconds of the detection of the transient peaks, in order to minimise errors due to the inevitable decay of voltage at the output of the detectors.

The values resulting from the conversion process are stored by the computer as four variables. A simple arithmetic sequence now calculates the peak-to-peak amplitude of vibration transient from each accelerometer, and determines the ratio of the two amplitudes for display as the required result of the test. Finally, the computer generates a pulse which resets the outputs of all the peak detectors to zero, in readiness for the next test.

The computer software allows entry of the patient's name, hospital number and date of fracture, together with the date of each test. This data, together with the test results, may be stored for subsequent use, or simply printed out at the end of each session. A single keyboard entry initiates the test sequence, and the programme automatically calculates the mean value of the test results whenever two or more tests are performed consecutively. Invalid test results, caused by vibration transients of insufficient or excessive amplitude, are detected, and the operator notifed accordingly. The computer may be programmed to perform a pre-determined number of tests consecutively on a given patient, without the need for operator intervention after each test.

The above bone analysis procedure may be used where the applied vibratory impulse is in the form of a mechanical impulse.

At first it appeared that the sine wave stimulus technique of the invention could be similarly handled directly by peak detecting hardware. However when the analysis was examined the problem turned out to be more complex than at first thought. The sine wave mode analysis does not use peak values which are easily captured by hardware, the values used are the peak to peak maxima. These maxima are considered to occur at comparable points in the recorded signals i.e they can be treated as the same event but observed after travelling by different routes. This led to a change of approach, and a second instrument has been developed that enables the assessment of tibia fractures by analysis of both impact and sine wave characteristics of the healing tibia, and makes considerable use of the flexibility provided by a micro-processor.

The basic design of the instrument incorporates three types of CPU boards, and is schematically shown in Figure 6.

The first is a CPU board 1. This provides all the control and analysis required by the application. The second board is a transient recorder. When activated the analogue input is digitised and stored in RAM and can be read out by the CPU 1. There are two transient recorder boards 2 and 3 in the unit to provide simultaneous capture of the data from the two accelerometers used to detect the bone response to enable the differences in natural mode frequencies with time to be monitored. The third board 4 is used to generate a stimulus signal in the form of an impulse or a sine wave output.

The CPU board has been designed around a Motorola 6809 CPU. The 6809 CPU was chosen in preference to the 8080/Z80 family of CPUs because of the availability of many support devices and for its ease of use. The 6809 contains its own clock oscillator, needing only an external crystal for operation. The support devices are in general simple to use both in hardware and software terms. The alternative CPUs are the 6800 and the 6502, either of these could have been used. The 6800 and the 6502 have very limited register sets and in view of the requirements of the instrument it was felt that the greater power of the 6809 CPU was needed.

The design of the 6809 CPU card includes both a serial interface, using a 6850 ACIA and a parallel interface, the GPIB interface, using a 68488. The serial interface will allow the unit to be used directly with a terminal or via an RS232 line to a control computer. The GPIB parallel interface is now a standard for connecting together several instruments all under the control of a computer. The PET computer uses a simplified version of the GPIB bus on its IEEE connector. There was a problem in obtaining several of the ICs required by the original design and so some features have not been fully realised.

The CPU board also contains a 6840 counter/timer IC. This device contains 3 counters which can be programmed to provide clocks for the system. One of the counters is linked to provide interrupts at regular intervals. This will eventually allow the unit to maintain its own time. The second counter is connected to the 6850 ACIA. The clock pulses produced are used by the 6850 to control its Baud rate i.e. the rate at which serial data is transmitted and received. The third counter is connected onto the unit's bus. This clock, sent along the bus, is intended to be used to control the sample rate of the transient recorders.

The remainder of the board contains three sockets. These sockets are to contain the operating software and RAM. The three sockets are intended to be used for either 2732 (4K PROM), 2764 (8K PROM), 6116 (2K RAM) or 6264 (8K RAM). There are links on the board that must be adjusted for each type of device used in the individual sockets.

There are some limitations on what device can be put in each socket. The first socket is for ROM only, 4K or 8K devices. The second socket can be set up to take 4K or 8K ROMs or an 8K RAM. The third socket can only take RAM, either 2K or 8K devices.

The standard input/output card, called a channel, is made up as follows:

There is a 2K window, DOOO to D7FF, which can be used for RAM if needed. This RAM can only be accessed after the channel has been enabled.

The transient recorder channels will use this window. To allow them to contain up to 32K of RAM some control lines are used to select which 2K bank is visible through the window. The transient recorder design does not allow for RAM devices with capacity greater than 16K.

There is a read/write register addressed in the range DCOO to DCFF, this is the CHANNEL REGISTER. This register when read gives the channel type (6 bits) and two status lines, these are normally linked to the PIA interrupt outputs to allow reading of the channel IRQ status directly. When the register is written to all eight bits are latched into a control register. The outputs from this register can then be used to control channel specific devices. A write to the channel register sets a bistable which enables the channel

RAM, general control register and the PIA for read/write operations. Writing to any other channel card register will disable the channel and enable the new channel.

The next register on a channel card is the GENERAL REGISTER. The general register is addressed in the range DD00 to DDFF. The general register can only be read after the channel has been enabled, however it can be written to at any time. This ability to write to the general register at any time means that all channel cards will receive the same information at the same time. The channel register allows individual control of the output lines, the general register allows coordinated control of several cards at the same time.

The last input output device on the card is a 6821 PIA. This is addressed in the range DE00 of DEFF. The PIA can only be written to or read after the channel has been enabled. The first and second locations make up the data registers of the PIA. The third and fourth locations are the control registers. This is to allow the PIA to be treated as a sixteen bit device. Data can be written to it as either eight bits, from the A or B registers or as sixteen bits from the D, X or Y registers etc.

The address lines are linked to the PIA in a non standard arrangement to give this type of access.

A0 is linked to RS1

A1 is linked to RS0

The two interrupt lines IRQA and IRQB are linked to the system bus IRQ line and to the channel register.

The current prototype cards do not have full address decoding so that the registers on the channel cards are duplicated throughout their address range.

Several channels are reserved for system applications. The reserved channel numbers are 0 and F0 to FE. One channel, 0, is reserved as a dummy, a write to it will disable all channels without causing control problems. All other channel numbers are to be used as access control to the individual cards.

There are four onboard I/O devices. These are used primarily for communications and control. The devices are the 6840, the 6850, the 68488 and a six bit, output only, latch linked to a row of LEDs. The latch can be used by the CPU to signal any errors found during a self test. One bit of the latch is reserved to allow the operating software to switch the system from a GPIB slave unit to a GPIB master unit. This option can be ignored and the CPU board hard wired as a master or a slave. A master can take control of the bus and use it to report the results or to take control of any other slave devices on the bus, e.g. there are many x- y plotters on the market with IEEE GPIB interfaces and such a plotter could be used to plot the result.

The onboard input/output devices only occupy the top thirty two bytes of the I/O block. The remaining section can be used for external input/output devices. These must all be addressable in the top section of the I/O block.

The above methods for assessing the mechanical properties of a healing tibia have involved the use of skin mounted accelerometers to detect the transmission of externally induced vibrations along the tibia. The effect of soft tissue between the accelerometers and the tibia attenuates the received signals, and careful placement and preloading of the transducers is necessary to obtain reproducible results.

An alternative technique, based upon Doppler ultrasound, to measure tibial vibrations may be employed, which is independent of the skin thickness and involves no preloading of the accelerometers.

Ultrasound striking a moving target will be reflected back to the transmitter changed in frequency by an amount given by:

$f_D = 2f_S v / c$

where f_D is the change in frequency (Doppler shift),

f_S is the frequency of the incident sound,

v is the velocity of the moving target, and

and c is the speed of sound in the medium between source target (approximately $1500 \mathrm{m\,s}^{-1}$).

If the target is vibrating sinusoidally then its velocity can be written as

$v = a_o w \sin wt$

where a_o is the displacement of the target at a time t. The maximum velocity is given by

$v_{max} = a_o w = 2\pi f a_o$

where f is the frequency of vibration of the target. Hence

$$f_D \max = \frac{2f_s v_{max}}{c}$$

and so

$$f_D \max = \frac{4\pi f f_s a_o}{c}$$

Hence by measuring the maximum Doppler shift frequency the amplitude of vibration may be determined. By suitable choice of f_s, f and amplitude of vibration of target a value for f_D in an acceptable range can be obtained.

With this method the tibia is vibrated as before at around the resonant frequency of the tibia. In this method the resulting vibrations along the tibia are detected using a 10 MHz continuous wave Doppler ultrasound detector. The ultrasound probe is coupled to the skin surface by a suitable water based gel and no preloading of the probe is necessary.

By placing the probe to either side of the bone fracture and measuring the respective maximum Doppler shift frequencies f_D above and below the break, it is possible to assess the rate of healing of the fracture.

The invention has been described in one of its best modes to the application of assessing the progress of a fractured bone to full union.

As indicated earlier however, the invention has general applicability to osseous systems and the assessment of structural and mechanicl integrity thereof which includes, as well as bone fractures, the investigation of the stability of composite systems where bone is in interface with implants or involving joint replacement.

CLAIMS

1. Apparatus for assessing the mechanical and structural integrity of bone such as bone fracture union comprising means for vibrating the bone, and means for monitoring the vibratory response from the bone to determine the presence of required mechanical and structural intergrity.

2. Apparatus as claimed in claim 1 wherein said monitoring means includes a pair of vibratory responding means for mounting to the body of a patient at either side of a bone fracture, said vibratory responding means being weighted or preloaded by an amount to compensate for damping effects caused by skin thickness on the vibratory signals received by each said vibratory responding means.

3. Apparatus as claimed in claim 2 wherein said vibratory stimulus is provided by mechanical impulse means, and said monitoring means further includes determining means for forming the ratio between the largest amplitude of the vibratory signal from each said vibratory responding means to provide at predetermined time intervals a measurable quantity against which to assess the process to completion of fracture union.

4. Apparatus as claimed in claim 2 wherein said vibratory stimulus is provided by means for delivering a continuous vibratory sinusoidal mechanical force to the bone, and said monitoring means further includes means for determining the difference between the first mode natural frequency of each component of the fractured skeletal element at predetermined time intervals to provide a measurable quantity against which to assess the progress to completion of fracture union.

5. Apparatus as claimed in claim 1 wherein said monitoring means comprises a pair of ultrasound detector probes for mounting to either side of a bone fracture.

6. Apparatus as claimed in claim 5 wherein said ultrasound probes are continuous wave Doppler ultrasound detectors, whereby the respective maximum Doppler shift frequencies above and below the fracture can be measured thereby to assess the rate of healing of the fracture.

7. Apparatus as claimed in claim 2 wherein said vibratory responding means is in the form of an accelerometer.

8. Apparatus as claimed in claim 2 wherein said preload as in the range 3.2 to 6 Newtons.

9. A method of assessing bone fracture union comprising applying vibratory stimulus to a fractured bone, and monitoring vibratory response from the bone thereby to determine progress to complete fracture union.

10. A method as claimed in claim 9 wherein the vibratory stimulus is carried out by applying an impulse to the bone, and a bone vibratory responding means is positioned to either side of the fracture, and weighting or preloading the vibratory responding means by an amount to compensate for the effects of skin thickness on the vibratory response therefrom.

11. A method as claimed in claim 10 wherein said monitoring is carried out by forming the ratio of the largest amplitude in signal recorded by that vibratory responding means on the other side of said fracture from the point of said stimulation to the bone to the largest amplitude in the signal recorded by the other vibratory responding means at predetermined intervals to provide a measure of the continuous process to complete fracture union in the bone.

12. A method as claimed in claim 10 wherein the vibratory stimulus is carried out by delivering a continuous vibratory sinusoidal mechanical force to the fractured bone, and a bone vibratory responding means is positioned to either side of the fracture, and weighting or preloading the vibratory responding means to compensate for the effects of skin thickness on the vibratory response therefrom.

13. A method as claimed in claim 12 wherein the differences are monitored between the first mode natural frequency of each component of the fractured skeletal element at predetermined time intervals to provide a measurable quantity against which to assess the progress of completion of fracture union of the bone.

14. A method as claimed in claim 9 wherein the vibration resulting from said vibratory stimulus, is monitored by ultrasound detector means.

15.A method as claimed in claim 14 wherein said ultrasound detector is a 10 MHz continuous wave Doppler ultrasound detector.

16. A method as claimed in claim 15 wherein said ultrasound probe is coupled to the skin surface by a suitable water based gel.

17. Apparatus for assessing the mechanical and structural integrity of osseous systems substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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